

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

Portal Instruments, Inc.,

Plaintiff,

v.

LEO Pharma A/S,

Defendant.

Case No.: 22-9156

**JURY TRIAL DEMANDED**

**COMPLAINT**

Plaintiff Portal Instruments, Inc. (“Portal” or “Plaintiff”), by and through its attorneys at Latham & Watkins LLP, brings this action against Defendant LEO Pharma A/S (“LEO” or “Defendant”) (together, the “Parties”), and alleges as follows:<sup>1</sup>

**STATEMENT OF THE CASE**

1. This case arises out of Defendant LEO’s failure to make contractually required payments to Plaintiff Portal under the parties’ Collaboration and License Agreement dated December 3, 2019 (the “Agreement,” attached hereto as Exhibit A).<sup>2</sup> Plaintiff Portal is a start-up company focused on developing innovative, needle-free drug delivery platforms to help patients with chronic diseases safely, quickly and reliably self-administer medications that improve their quality of life.

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<sup>1</sup> Based on discussions with the Clerk’s Office regarding proper filing protocol, Portal has redacted certain portions of the Complaint that it believes could be subject to a confidentiality agreement entered into with LEO. Upon issuance of a summons and assignment of this case to a specific Judge, Portal intends to promptly serve its Complaint on LEO and file a sealed version with the appropriate motion in accordance with the Judge’s preferred procedures.

<sup>2</sup> Portal will seek leave to file the intended exhibits under seal once a judge has been assigned to this matter, so that Portal can comply with the judge’s individual rules on sealing.

2. In December 2019, Portal and the pharmaceutical giant LEO entered into an agreement whereby LEO agreed to pay Portal in installments to fund the development of a drug delivery system for LEO's products. Portal worked diligently to develop this system, but LEO abruptly changed its mind and cancelled the program, refusing to make development payments it had contractually pledged to make even while it admitted to be pleased with Portal's work and terminating without cause.

3. LEO also pledged to make milestone payments to Portal if its product achieved certain benchmarks in testing. Portal's product hit its benchmark, but LEO refused to make this payment as well.

4. Portal's first count alleges that LEO breached the parties' contract by failing to make a [REDACTED] quarterly installment payment required by Section 7.2 of the Agreement. Portal's second count alleges that LEO separately breached the parties' contract by failing to make a [REDACTED] milestone payment required by section 7.3 of the Agreement. Portal's third count alleges that LEO breached its implied covenant of good faith and fair dealing by failing to make the \$[REDACTED] installment payment and the [REDACTED] milestone payment. Portal seeks damages for these breaches of no less than \$[REDACTED], plus fees and prejudgment interest.

### **PARTIES**

5. Plaintiff Portal is a corporation that is incorporated in Delaware and has its principal place of business in Cambridge, Massachusetts. Portal is a biotech company focused on developing a needle-free drug delivery platform. This platform, based on technology developed at MIT, would allow patients with chronic diseases to administer their own medication at home without the use of needles – which are inconvenient, difficult to use and dispose of, hazardous to children, and a source of fear or anxiety for many patients.

6. Upon information and belief, Defendant LEO is a corporation organized under the laws of the Kingdom of Denmark and has its principal place of business in Ballerup, Denmark. LEO is a pharmaceutical company engaged in the research, development and commercialization of therapeutic drugs useful in the amelioration, treatment and/or prevention of human diseases and conditions.

### **JURISDICTION AND VENUE**

7. This court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(2) because the action is brought by a citizen of a state within the United States against a citizen of a foreign state, and the matter in controversy exceeds the sum or value of \$75,000 exclusive of costs and interest.

8. This Court has personal jurisdiction over LEO pursuant to C.P.L.R. § 302 and General Obligations Law § 5-1402 because this action arises out of the Agreement between the Parties. The Agreement is governed by New York law and reflects the Parties' consent to the jurisdiction of the state or federal courts of New York. Section 14.11(c) of the Agreement stipulates:

THE PARTIES IRREVOCABLY ACCEPT THE EXCLUSIVE JURISDICTION OF [NEW YORK] COURTS SOLELY AND SPECIFICALLY FOR THE PURPOSE OF ADJUDICATING DISPUTES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND ANY OTHER AGREEMENT ENTERED INTO PURSUANT HERETO OR IN CONNECTION HEREWITH (INCLUDING MATTERS REGARDING THE CONSTRUCTION, INTERPRETATION AND ENFORCEABILITY OF SUCH AGREEMENTS), AND IN NO EVENT SHALL ANY PARTY BE DEEMED TO HAVE CONSENTED TO SUCH JURISDICTION FOR ANY OTHER PURPOSE. EACH PARTY FURTHER AGREES THAT SUCH COURTS PROVIDE A CONVENIENT FORUM FOR ANY SUCH ACTION, AND WAIVES ANY OBJECTIONS OR CHALLENGES TO VENUE WITH RESPECT TO SUCH COURTS.

9. Venue is proper in this county pursuant to 28 U.S.C. 1391(c)(2) because this action arises out of a contract pursuant to which the parties have agreed to submit to the laws and jurisdiction of the State of New York.

### **FACTS**

#### **A. Development of the 1x2ml System**

10. On December 3, 2019, the Parties entered into the Agreement. The purpose of the Agreement was for the parties to jointly develop a variety of drug delivery systems that could be used by patients taking LEO's drugs. Under the Agreement, LEO agreed to make a one-time payment to Portal, a series of installment payments once Portal began developing one or more drug delivery systems, and a variety of milestone payments triggered by specific events in the development process.

11. Under the Agreement, LEO could request that Portal develop either (1) a drug delivery system capable of delivering 2mL of LEO's drug in a single injection (the "1x2mL System"), (2) a drug delivery system capable of delivering 2mL of LEO's drug in two sequential injections (the "2x1mL System"), or (3) both systems.

12. The Agreement obligated LEO to elect one of the three options in the foregoing paragraph and required LEO and Portal to "use Commercially Reasonable Efforts to collaborate in Developing the Product." Agreement § 4.1 (Ex. A). The Agreement also allowed LEO to, "any point after making its election pursuant to this Section 4.2, in its sole discretion, provide Portal with written notification to change its election, including to cease and/or commence to Develop a System under the Development Plan." *Id.* § 4.2.

13. Section 7.2(a) of the Agreement stated that, in the event that LEO elected to develop the 1x2mL System, LEO agreed to pay [REDACTED] to Portal in the form of ten quarterly payments of [REDACTED] each (the "Development Fee"). Agreement § 7.2(a) (Ex. A). Pursuant to Section

7.2(a) of the Agreement, the Development Fee was due at the beginning of the respective calendar quarter.

14. In the event that LEO wished to terminate the Agreement, or the development of any product under the Agreement, Section 17.2(a) required LEO to provide Portal with “ninety (90) days’ prior written notice.” This notice requirement applied whether LEO chose “to terminate the Agreement in its entirety, on a Product-by-Product basis, or on a county-by-country [sic] basis.”

15. LEO elected to begin development of the 1x2mL System in early January 2020, and Portal began working on the 1x2mL System at that time.

16. Based on LEO’s election and representations, Portal allocated substantial resources towards the development of the 1x2mL System, including hiring several employees and incurring extensive front-end development costs.

17. On April 3, 2020 LEO confirmed in writing that it would be developing the 1x2mL System, which under the terms of the Agreement obligated LEO to make a total of ten quarterly R&D payments to Portal, including for the first quarter of 2020. LEO and Portal agreed that LEO would make payments on the following schedule:

Payment	Due Date	Amount
First Quarterly Payment	01/01/2020	██████████
Second Quarterly Payment	04/01/2020	██████████
Third Quarterly Payment	07/01/2020	██████████
Fourth Quarterly Payment	10/01/2020	██████████
Fifth Quarterly Payment	01/01/2021	██████████
Sixth Quarterly Payment	04/01/2021	██████████

Seventh Quarterly Payment	07/01/2021	██████████
Eighth Quarterly Payment	10/01/2021	██████████
Ninth Quarterly Payment	01/01/2022	██████████
Tenth Quarterly Payment	04/01/2022	██████████

18. LEO made seven quarterly payments to Portal, comprising the four quarters of 2020 and the first three quarters of 2021.

19. Throughout 2020, and the first three quarters of 2021, LEO's and Portal's teams worked closely together to develop the 1x2mL System.

**B. LEO's Termination of the Agreement**

20. On September 15, 2021, LEO provided Portal with a termination notice ("Termination Notice," attached hereto as Exhibit B), announcing that the Agreement would be terminated "with effect as of December 22, 2021" – 90 days after the Termination Notice was provided.

21. The Termination Notice asserted that LEO was electing to "cease the Development of the 1x2mL System" with "immediate effect," and that it had "no obligation to make any future installment payments towards the 1x2mL System Development Fee." Termination Notice (Ex. B).

22. LEO delivered the Termination Notice with no prior notice or indication to Portal other than a prior-day phone call.

23. Upon sending the Termination Notice, LEO informed Portal that it was pleased with Portal's performance and was not terminating the Agreement and development of the 1x2mL



System for cause, but that LEO had chosen to go in a different direction with respect to its product development.

24. Per the Agreement, whether LEO chose “to terminate the Agreement in its entirety, on a Product-by-Product basis, or on a county-by-country [sic] basis,” it was required to provide “ninety (90) days’ prior written notice.” Agreement § 17.2(a) (Ex. A).

25. Therefore, LEO’s termination of the Agreement was effective as of December 22, 2021.

26. Likewise, LEO’s termination of the development of the 1x2mL System was effective as of December 22, 2021.

27. After providing the Termination Notice, LEO did not provide Portal payment of the Development Fee installment due for the fourth quarter of 2021 (the period October 1, 2021 to December 31, 2021) (the “8th Quarterly Payment”).

**C. LEO Breached the Agreement by Not Making the 8th Quarterly Payment**

28. The 8th Quarterly Payment was due on October 1, 2021.

29. The 8th Quarterly Payment covers the period October 1, 2021 to December 31, 2021 (i.e., the 8th of 10 quarterly periods contemplated by Section 7.2(a) of the Agreement).

30. Section 7.2(a) of the Agreement further provides that, following LEO’s termination of the development of the 1x2mL System, it “shall have no obligation to make any future installment payments towards the 1x2mL System Development Fee.”

31. LEO’s termination of the 1x2mL System’s development had not taken effect at the time that the 8th Quarterly Payment was due.

32. New York Law governs the Agreement.

33. Under New York law, all contractual obligations – including payments – remain in effect during the period between the notice of contract termination and the effective date of termination.

34. The 8th Quarterly Payment is not a “future installment payment” in the meaning of Sec. 7.2(a) of the Agreement, since it was due well before the 1x2mL System’s development was terminated effective December 22, 2021, and because it is for the period October 1, 2021 to December 31, 2021, during which period the Agreement was in effect.

35. As is common industry practice, the Parties’ clear intent, in requiring a 90-day pre-termination notice period in Sec. 17.2(a), and requiring that installment payments be made at the beginning of each quarter, was to allow Portal time to wind down its development program upon notice of termination while not immediately losing its right to compensation for ongoing work during the notice period and as Portal wound down the project.

36. The Agreement required LEO to pay Portal the 8th Quarterly Payment of [REDACTED] on October 21, 2021.

37. As of the filing of this action, LEO has not made any Development Fee payments to Portal beyond the 7th of 10 quarterly payments. LEO has not paid Portal the 8th Quarterly Payment.

**D. The Milestone Payment and Milestone Event**

38. In addition to LEO’s failure to pay the 8th Quarterly Payment, LEO committed additional and distinct breaches of the Agreement. Separately from the Development Fee, LEO also promised to pay Portal one-time incentive payments for completing certain milestones in the development of the 1x2mL System (the “Milestone Payments”).

39. Under Section 7.3 of the Agreement, LEO was obliged to “make the following non-refundable, non-creditable Milestone Payments (the “Milestone Payments”) to Portal within forty-



five (45) days after achievement of the relevant milestone set out below.” Section 7.3 also contained a table of relevant milestones and their associated payments.

40. Section 7.3 of the Agreement stated that, if Portal completed “a pharmacokinetic study in animals in which a Third Party determines that [REDACTED] [REDACTED],” (the “Milestone Event”) LEO would be obligated to make a Milestone Payment of [REDACTED] to Portal as long as the study included a “[REDACTED] and descriptions of attainment of pharmacokinetic endpoints and such safety experience as [had] been observed.”

41. Under Section 4.1 of the Agreement, LEO had “primary control and direction in the Project” when “planning, funding and executing all Clinical Trials and other clinical Development activities related to the Product,” but was obligated to “use Commercially Reasonable Efforts” with respect to such trials.

42. In February 2021, a third party, Charles River Laboratories (“CRL”) completed a pharmacokinetic bioequivalence study on animals (“PK Study”) using the 1xmL System as specified in the Agreement.

43. A formal bioequivalence study typically requires a crossover design, which means that test subjects receive both types of treatments in the study.

44. The FDA guidance for bioequivalence studies of this nature allows them to be conducted in a non-crossover manner, but in that case, the study can only look at the average results across each tested group as a surrogate finding for bioequivalence.

45. LEO [REDACTED]  
[REDACTED]  
[REDACTED].

**E. LEO Was Obligated to Make the Milestone Payment**

46. After completion of the study, LEO acknowledged orally that the Milestone Event had been achieved and that it would make the Milestone Payment as soon as CRL issued its final report.

47. On June 15, 2021, CRL's pharmacokinetic lead Oriel Peris signed the PK Study report. On the same day, CRL shared the report with LEO.

48. Section 6.1 of the PK Study report states that [REDACTED]

[REDACTED]. In Section 6.2, named "Pharmacokinetic Evaluation," it further states that [REDACTED]. This was based on maximum drug concentration ( $C_{\max}$ ) and on the integral of the concentration-time-curve ( $AUC_{(0-\infty)}$ ).

49. Lastly, it concluded [REDACTED]

50. These conclusions are [REDACTED], confirming that the Milestone Event had been achieved (as LEO had previously admitted) and triggering LEO's duty to make the Milestone Payment.

**F. LEO Breached the Agreement by Not Making the Milestone Payment**

51. Despite the study's findings, LEO did not make the [REDACTED] Milestone Payment. As such, it committed a separate and independent breach of the Agreement, specifically Section 7.3 of the Agreement.

52. In an attempt to avoid making the Milestone Payment, [REDACTED]

[REDACTED], LEO asserted that the PK Study had not found bioequivalence and that the Milestone

Event had not been achieved, notwithstanding a separate study having already confirmed such bioequivalence.

53. LEO's [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]. Through these tactics, LEO intentionally skewed the PK Study data, which LEO then attempted to use to claim bioequivalence criteria had not been found.

54. LEO also [REDACTED]

[REDACTED], again, in order to drive a conclusion that could potentially avoid its contractual obligations to make the Milestone Payment.

55. The true motivations behind LEO's study were later revealed and confirmed. As Portal ultimately discovered, at or around the time the Milestone Event was achieved, LEO had already changed its business plans, and thus wanted to lower all expenses incurred under the Agreement. In an attempt to do so, LEO [REDACTED]  
[REDACTED] so as to avoid paying Portal the [REDACTED] Milestone Payment.

56. Notwithstanding this bad faith attempt to avoid payment, LEO's post-hoc analysis is ultimately irrelevant to its obligations under the Agreement, since the Milestone Event is defined as based on a third party report concluding bioequivalence (or its surrogate), not LEO's own interpretation of the third party study.

57. Moreover, although driven by an attempt to avoid a payment owed, [REDACTED]

[REDACTED]

58. FDA guidance states that when a drug is delivered at concentrations above the bioequivalence level, it will still pass a bioequivalence test as long as the amount delivered is within safety margins – which it was in this case. But LEO did not acknowledge or consider this guidance when claiming that Portal’s product had not achieved bioequivalence.

59. All aspects of the PK Study show that LEO intentionally structured the study and its analysis to avoid making a payment that it knew it owed. First, LEO [REDACTED]

[REDACTED]

Second, when their own study design showed that Portal had achieved bioequivalence, LEO [REDACTED]

[REDACTED]. Third, after even [REDACTED] showed that the milestone had been achieved, LEO continued to deny it and refused to make the payment.

60. Thus, the Milestone Event was completed, triggering LEO’s obligation to make the Milestone Payment. The Milestone Payment was to be made within 45 days, i.e. no later than July 30, 2021.

61. As of the filing of this action, LEO has not made the Milestone Payment.

\* \* \* \*

### **FIRST CAUSE OF ACTION**

#### **Breach of Contract: Non-Payment of Development Fee**

62. The allegations contained in paragraphs 1-37 above are incorporated herein as if fully set forth below.

63. The Agreement is a valid and binding contract.

64. Pursuant to Section 7.2(a), the 8th Quarterly Payment was due at the beginning of the fourth quarter of 2021, on October 1, 2021. The Agreement was in effect on October 1, 2021 and for approximately 12 weeks thereafter.

65. LEO failed to make the 8th Quarterly Payment as contractually obligated.

66. By failing to make the 8th Quarterly Payment, LEO breached its contractual obligations.

67. By reason of the foregoing, LEO is liable for [REDACTED] plus interest and attorneys' fees and costs.

## **SECOND CAUSE OF ACTION**

### **Breach of Contract: No Payment of Milestone Payment**

68. The allegations contained in each preceding paragraph above are incorporated herein as if fully set forth below.

69. The Agreement is a valid and binding contract.

70. Section 7.3 of the Agreement obligates LEO to make the Milestone Payment within 45 days after the Milestone Event has been achieved.

71. Portal achieved the Milestone Event.

72. Although the Milestone Payment obligation was triggered through completion of the Milestone Event, LEO did not make the Milestone Payment in due time, thus breaching the Agreement.

73. By reason of the foregoing, LEO is liable in the amount of [REDACTED] plus interest and attorneys' fees and costs.

### **THIRD CAUSE OF ACTION**

#### **Breach of Implied Covenant of Good Faith and Fair Dealing**

74. The allegations contained in each preceding paragraph above are incorporated herein as if fully set forth below.

75. The Agreement, like all contracts, contains an implied covenant of good faith and fair dealing.

76. LEO did not act fairly and in good faith when it informed Portal of its intent terminate the Agreement and then refused to make any further payments in the period after providing notice of intent to terminate but before that termination was effective.

77. As LEO knew and intended, Portal made long term resource allocations and entered long term agreements with employees and suppliers when it began working on the 1x2mL System. The parties did not agree, or intend, that while Portal had such obligations, including performance during the 90-day notice period, LEO would be able to provide 90-day notice of intent to terminate development of the 1x2mL System yet have no obligation to compensate Portal during that 90-day period.

78. By refusing to make the 8th Quarterly Payment, despite knowing that the Agreement continued in full force and effect for the 90-day period between notice and termination, LEO breached its covenant of good faith and fair dealing.

79. LEO also did not act fairly and in good faith when it designed the PK Study to avoid having to admit that the 1x2mL System had achieved bioequivalence.

80. LEO also did not act fairly and in good faith when it [REDACTED] [REDACTED] to avoid the [REDACTED] Milestone Payment. LEO represented to Portal that it intended to perform under the Agreement, when in fact it had already decided to change its business plans and subsequently avoid all payments towards Portal.



81. LEO took these bad faith actions in order to avoid payment obligations that were due and owing under Sections 7.2 and 7.3 of the Agreement, depriving Portal of the benefit of its bargain.

82. By reason of the foregoing, LEO is liable in the amount at least [REDACTED], plus additional damages to be determined at trial, plus interest and attorneys' fees and costs.

**PRAYER FOR RELIEF**

**WHEREFORE**, Portal respectfully requests judgment as follows:

1. Awarding Portal compensatory damages resulting from LEO's breach of contract in an amount to be determined at trial;
2. Awarding Portal compensatory damages resulting from LEO's breach of the implied covenant of good faith and fair dealing in an amount to be determined at trial;
3. Awarding Portal its attorneys' fees, costs and disbursements incurred in connection with its efforts to enforce the Agreement;
4. Awarding prejudgment interest to be proved at trial;
5. Granting such other relief as the Court deems just and proper.

Dated: October 25, 2022  
New York, New York

Respectfully submitted,

**LATHAM & WATKINS LLP**

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